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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,935	03/06/2002	Adi Shefer	4686-110 US	7056

7590 09/19/2005

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,935	SHEFER ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2005* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7-33,35,36,38-42 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-33,35,36,38-42 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' amendment, filed 06/09/2005; and request for RCE, filed 07/01/2005.

Claims 2, 3, 6, 34, 37, and 43-46 have been canceled.

Claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/01/2005 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 4, 5, 7-33, 38-41, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claim 1 recites the broad recitations "carbohydrate", and the claim also recites "starch" and "cellulose" which are specific and narrower statement of the range/limitation. Further, claim 1 recites the broad recitations "starch", "starch derivatives", and "modified starches", and the claim also recites "starch hydrolyzate" and "hydroxyalkyl starches" which are specific and narrower statement of the range/limitation.

Regarding claims 27 and 32, the claims recite "antioxidant" and "free-radical scavenger" which have overlapping scope, and recourse to the specification does not define the expressions "antioxidant" or "free-radical scavenger" to show the distinctness. Clarification is requested.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 4, 5, 7, 8, 10, 13-18, 20, 21, 27, 29, 30, 32, 35, 36, 38-42 and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0027833 ('833), with the effective filing date of May 07, 2001.

US '833 discloses pharmaceutical composition in the form of single adhesive polymeric layer, film or matrix that deliver local anesthetic agent to the skin (abstract; page 2, paragraphs 0014-0017; page 9, paragraph 0091). The polymeric layer is water-soluble and can be removed easily by application of water, and selected from PVP, PVA, hydroxypropyl cellulose, starch and starch derivatives with a pharmaceutically active agent homogenously admixed therein with a permeation enhancer (page 2, paragraphs 0021, 0023; page 6, paragraph 0070, 71; page 7, paragraphs 0077, 0078). The polymeric layer further comprising bactericidal agent selected from iodine, silver, mercury compounds, phenol and chlorhexidine (page 4, paragraph 0051); antibiotic including tetracycline (page 4, paragraph 0052); capsaicin, and peptide or proteins (page 4, paragraphs 0053, 0055); mineral oils (page 7, paragraph 0074); excipients including colorant (therefore the patch is colored), plasticizer, antioxidants, pH regulators, menthol and glycerol (page 6, paragraph 0064; page 8, paragraph 0083-0087). Part of the active agent could be encapsulated within liposomes (page 5, paragraph 0060). The active agent is delivered within 10 minutes and lasts up to 6 hours (page 2, paragraph 0026). The polymeric film has thickness of 0.01 mm to 2 mm (page 7, paragraph 0076).

6. Claims 1, 4, 5, 9, 11-18, 20, 21, 26, 27, 29, 30, 32, 38, 42, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2003/0107149 ('149) with the effective filing date October 12, 2001.

US '149 discloses film for topical application to skin wherein the film disintegrates in water (abstract; page 10, paragraph 0154). The film comprising water-soluble polymer with active agent uniformly dispersed therein (page 4, paragraphs 0060, 0062). The water soluble-polymer comprises PVP, PVA, or hydroxypropyl cellulose (page 5, paragraph 0083). The active agent includes analgesic such aspirin and ibuprofen, anesthetic, anti-histamine, anti-infective agents, and amino acids (page 7, paragraphs 0099-0101). The polymer film further comprises colorants (therefore the patch is colored), sodium carbonate and sodium bicarbonate, menthol, plasticizers, release modifiers, glycerol and propylene glycol (page 7, paragraphs 0098, 0104-0108; page 8, paragraphs 0118-0123). The film has thickness of 500-1500 μm (page 10, paragraph 0152). The active particles can be coated to achieve controlled release (page 6, paragraph 0092).

7. Claims 33, 35, and 36 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US 2001/0007671 ('671), with the effective filing date of July 29, 1999.

US '671 discloses a cosmetic, pharmaceutical, or dermatological patch for application of active agent to the skin (abstract; page 1, 0012, 0015). The patch imparts great softness, freshness and coolness and easily manipulated during application and

removal from the skin (page 1, paragraph 0007). The patch includes a water-polymer matrix layer comprising an active agent and polymer including hydroxypropyl cellulose which is inherently water soluble (Figures 1; page 2, 0017, 0018, 0024, 0035; page 3, 0046; page 7, claim 15; page 8, claims 67-70). The skin can pre-wetted prior to application of the patch (page 1, 0014). The composition is homogenous, i.e. active substance uniformly distributed through out the matrix layer (page 1, 0014; Figure 2, A-C). The active agents include anti-oxidants, free-radical scavengers, moisturizers, bleaching agents (depigmentation agents), liporegulators, anti-acne agents, anti-aging agents, anti-wrinkle agents, anti-inflammatory agents, softeners, keratolytic agents, anti-bacterials, anti-fungal, antiperspirants, deodorants, skin conditioners, immunomodulators, nourishing agents, moisture absorbers and sebum absorbers (page 3, 0046, 0047). The patch is transparent or colored (page 2, 0020; page 3, 0050). The composition includes acetylsalicylic acid (aspirin) (page 3, 0047). The composition comprises solvent, such as propylene glycol (page 3, 0045). The composition comprising sodium carbonate and sodium bicarbonate (page 3, 0043). The patch is applied to the skin from about few seconds to about few days (page 1, 0015). The composition also comprises mineral oils (page 2, 0038). The composition further comprises salicylic acid which is a keratolytic agents (page 3, 0048; page 8, claim 60). The composition also comprises isopropanol (page 3, 0045).

8. Claims 33, 35 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,419,935 ('935) with the effective date of July 29, 1999.

US '935 disclosed cosmetic skin treatment method includes providing a patch with good adhesiveness without drying the skin that includes a single polymeric matrix that includes at least one cosmetically active compound (abstract; col.1, lines 43-57; col.2, lines 49-57; col.9, lines 66-67). The patch is configured to adhere to the dry skin and to the moistened skin to provide treatment and cleansing the skin (abstract; col.2, lines 1-3, 57-59; col.3, lines 12-14). The patch provides treatment when one or more cosmetically active compounds are released onto the epidermis when the patch is applied for time ranging from 5 minutes to 60 minutes (col.2, lines 8-12; col.4, lines 64-67). The polymeric matrix includes polyvinyl alcohol, starches, cellulose derivatives, which are inherently bioadhesive, water soluble and film forming polymers (col.6, lines 1-6; col.7, lines 1-12). The cosmetically active compounds to be incorporated in the matrix include moisturizers, keratolytic agents, anti-wrinkle agents, self tanning agents, bleaching agents and lightening agents (depigmentation agents), antioxidants, free-radical scavengers, liporegulators, anti-acne agents, anti-aging agents, anti-inflammatory agents, steroidal anti-inflammatory agents, refreshing agents, antibacterials, antifungals, and nourishing agents (col.4, lines 23-34; col.5, line 36). The active compound is dispersed homogenously in the polymeric matrix (col.4, lines 35-36). Antibacterials disclosed by the reference include tetracyclines, erythromycin, and clindamycin (col.5, lines 3-4). The keratolytic agents include salicylic acid (col.4, line 61 till col.5, line 1). The active compounds include acetylsalicylic acid (aspirin) (col.5, lines 20-21). The patch comprises mineral oils and lanoline, and agents selected from glycerol, propylene glycol, and sorbitol (col.5, lines 36-49). The patch further comprising

agent selected from clove oil or menthol (col.7, lines 24-28). The tanning agents include dihydroxyacetone (col.5, lines 62-65). The polymeric matrix is colored (col.8, lines 35-37). The patches are cut to shapes designed to fit on various parts of the body and the preferred size ranges from 1 cm^2 to 30 cm^2 (col.9, lines 6-18). The polymeric matrix forms a layer having a thickness of 0.2 mm (col.9, lines 66-67).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 9, 11, 12, 19, 22-26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '833 in view of US '671.

The teachings of the references are discussed above.

However US '833 does not teach the inclusion of specific active agents in the polymer film, the film is transparent, or wetting the film before application to the skin, which all disclosed by US '671.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide soluble film to deliver active agent to the skin as disclosed by US '833 and select the active agent suitable for delivery to the skin or that treat topical skin conditions, and select the patch to be transparent and wet the skin before its application as disclosed by US '671, motivated by the teaching of US '671 that patch with these characteristics and contents imparts great softness, freshness and coolness and easily manipulated during application and removal from the skin, with reasonable expectation of delivering wide varieties of beneficial active agent to the skin from transparent easily manipulated film.

12. Claims 9, 19, 22-25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '149 in view of US '671.

The teachings of the references are discussed above.

However US '149 does not teach the inclusion of specific active agents in the polymer film, the film is transparent, or wetting the film before application o the skin, which all disclosed by US '671.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide soluble film to deliver active agent to the skin as disclosed by US '149 and select the active agent suitable for delivery to the skin or that treat topical skin conditions, and select the patch to be transparent and wet the skin before its application as disclosed by US '671, motivated by the teaching of US '671 that patch with these characteristics and contents imparts great softness, freshness and coolness and easily manipulated during application and removal from the skin, with reasonable expectation of delivering wide varieties of beneficial active agent to the skin from transparent easily manipulated film.

13. Claims 9, 11, 12, 22-26, 28, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '833 in view of US '935.

The teachings of the references are discussed above.

However US '833 does not teach the inclusion of specific active agents in the polymer film, wetting the film before application o the skin, and the size of the patch, which all disclosed by US '935.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide soluble film to deliver active agent to the skin as disclosed by US '833 and select the active agent suitable for delivery to the skin or that treat topical skin conditions, and select the patch to be with the specific size, and wet the skin before its application as disclosed by US '935, motivated by the teaching of US '935 that the disclosed patch and its method of use provides good adhesiveness without

drying the skin, with reasonable expectation of delivering wide varieties of beneficial active agent to the skin from dissolvable film that has good adhesiveness without causing drying of the skin.

14. Claims 9, 22-25, 28 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '149 in view of US '935.

The teachings of the references are discussed above.

However US '149 does not teach the inclusion of specific active agents in the polymer film, wetting the film before application o the skin, and the size of the patch, which all disclosed by US '935.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide soluble film to deliver active agent to the skin as disclosed by US '149 and select the active agent suitable for delivery to the skin or that treat topical skin conditions, and select the patch to be with the specific size, and wet the skin before its application as disclosed by US '935, motivated by the teaching of US '935 that the disclosed patch and its method of use provides good adhesiveness without drying the skin, with reasonable expectation of delivering wide varieties of beneficial active agent to the skin from dissolvable film that has good adhesiveness without causing drying of the skin.

15. Claims 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US '833 or US '149.

The teaching of US '833 and US '149 are discussed above.

However, the references do not teach the size of the patch.

It would have been obvious to one having ordinary skill in the ad at the time the invention was made to have a polymer film or patch with a size between 1 cm^2 to 30 cm^2, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable / ranges involves only routine skill in the art. *In re Aller* 105 USPQ 233.

Response to Arguments

16. Applicant's arguments with respect to claims 1, 4, 5, 7-33, 35, 36, 38-42, and 47 have been considered but are moot in view of the new ground(s) of rejection.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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